MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

November 9, 2016

Ms. Barbara Cunningham (7401M)
Deputy Director for Management and Pollution Prevention
Office of Pollution Prevention and Toxics
Environmental Protection Agency
William Jefferson Clinton Building 1200
Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Barbara:

Based on reports obtained from a number of the American Chemistry Council's (ACC) members, I wanted to raise several concerns with EPA's implementation of section 14 of the Lautenberg Chemical Safety Act (LCSA). In our view, the Agency's approach threatens to reveal company confidential business information (CBI) and jeopardizes the protection of additional information that warrants protection. In light of the industry's recent experience, we recommend that EPA temporarily cease its substantiation practices until a clear process and associated guidance to the chemical industry is available.

In addition to the significant substantive concerns outlined below, we have identified some other suggestions in this letter that we believe will improve and streamline EPA's process to substantiate CBI claims.

A. Significant Concerns

Section 14(c) of the Toxic Substances Control Act (TSCA) as amended by LCSA requires all CBI claims to be asserted by the claimant, and, for certain CBI claims, requires up-front substantiation of the claim. Section 14(g) requires EPA to make a determination on claims to protect CBI within 90 days. Although it is not clear whether EPA has in fact made any CBI determinations since the date LCSA was enacted on June 22, 2016, EPA's general practice of responding to CBI claims with a further substantiation request has produced significant confusion.

Section 14(g)(1)(C) requires EPA to review all claims to protect chemical identity from disclosure, and at least 25 percent of all other CBI claims. Based on reports from our members, EPA has indicated that it is **not** reviewing CBI submissions in advance of issuing requests for substantiation. Our understanding is that EPA is reflexively responding to CBI claims by

sending detailed substantiation requests back to companies rather than reviewing the claim as made in the original submission. This approach is certainly not contemplated by the LCSA amendments and do not comport with EPA's own regulations at 40 C.F.R. 2.204(b). Importantly, the approach EPA is taking is unduly burdensome for both the Agency and the industry.

Substantiation requests received by ACC member companies run as long as 26 questions, some of which are not relevant to the specific information claimed confidential or substantiating that particular request. This has created significant confusion, as it is not clear if EPA expects all substantiation requests to be answered.

EPA's substantiation requests are often confusing and would benefit from greater clarity regarding what EPA is actually requesting. For example, companies have received requests for substantiation of a "submission made on X date" without any detail regarding the specific submission. Some companies make multiple submissions to EPA on any given day and will not know or understand on which submission EPA is requesting substantiation if only a date is provided. In another example, a company received a substantiation request for a CDR submission that referred to an internal EPA number, leaving the company entirely uncertain regarding which document was the subject of the substantiation request.

In some cases, substantiation requests are simply not warranted. We are aware that companies that filed a low volume exemption (LVE) that was subsequently denied have received a CBI substantiation request for the claims in the LVE. It does not make any sense for the CBI substantiation to be made for an LVE that has been denied. A substantiation request should not be sent to a company unless and until the LVE is approved.

ACC is aware of several cases where a request for substantiation was addressed to and received by a company that was not the intended recipient/CBI submitter. In these cases, the CBI submitter had no affiliation whatsoever with the actual recipient company. Although the substantiation request was subsequently forwarded to the intended company, this incident raises significant concerns about the potential to disclose confidential information to parties not entitled to receive it.

In another case, an ACC member company received a request to substantiate CBI claims for a Notice of Commencement (NOC) for which it had already provided upfront substantiation and certification in its NOC. Included in the substantiation material from EPA was confidential information regarding another company's premanufacture notice (PMN), which was not redacted. The documentation detailed how the material will be used, the CAS numbers and chemical names of analogues, the site where the material will be manufactured/used, etc. It would appear to not be routine EPA practice to include such material with a substantiation request.

ACC members also report that CBI substantiation requests are frequently not mailed to the company technical contact who is identified on relevant CBI claim documents. In some cases, the requests have been addressed to people who are not employed by the company, and in other

instances, the correspondence is addressed only to the company or a site, with no particular person named as the addressee. These errors delay the circulation of the substantiation requests to the appropriate personnel, reducing the already short timeframes allotted by EPA for response.

ACC believes this approach – and the errors it has engendered – warrants reconsideration. We strongly recommend that EPA temporarily cease its CBI substantiation-related activities, take stock of its approaches, and implement a system that eliminates the potential for error and disclosure (however inadvertent). An assessment of the scope of the CBI substantiation process will save scarce Agency resources and avoid the duplication of work by industry.

ACC is also very concerned that EPA is misreading its section 14 authority regarding CBI disclosures. Several member companies have received substantiation correspondence from EPA that claims that "[a]ny information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed without further notice." This statement erroneously suggests that only a response to a substantiation qualifies information for protection from disclosure, and ignores completely the section 14 requirements that CBI information can only be disclosed upon written notice to the claimant.

B. Suggestions for Improving the Substantiation Process

Section 14(c) of LCSA identifies specific information for which a claim of confidentiality must be asserted, but for which substantiation is not required. In Appendix A to this letter, we have identified the data fields in the Chemical Data Report (CDR) and PMN submissions which should not require substantiation under the law.

In addition, ACC believes that a wide range of information claimed as confidential in a PMN should not require substantiation until a NOC is filed for the substance. The rationale for protecting confidential chemical identity in a PMN applies equally as well to any other information (e.g., company identity) prior to commencement of manufacture. We note that section 14 imposes no barrier to EPA expanding the set of information for which assertion of the claim is the only requirement in the context of a PMN.

Similarly, ACC believes that notices of "bona fide intent" submitted by a manufacturer/importer to determine if a substance is on the confidential inventory should not be subject to substantiation requirements. If the chemical is on the confidential inventory, its confidentiality has been established previously. If the chemical is not on the Inventory, then EPA should await the submission of the NOC before requiring substantiation.

As ACC has noted in past correspondence, we believe EPA should adopt a policy of protecting full health and safety study reports that have significant commercial value, but release to the public all relevant health and safety effects information in robust study summaries. This policy has been adopted or utilized successfully by other foreign regulatory agencies, such as the European Chemicals Agency (ECHA) and Health Canada. EPA could agree to permit academics or other interested parties to have limited access to the full health and safety study reports by signing a binding non-disclosure agreement if that were deemed necessary. ACC believes this

policy would correctly balance the interests of public transparency with the interests of businesses seeking to protect the often significant commercial value of full proprietary health and safety studies.

LCSA also requires EPA to implement a system of unique identifiers for confidential chemical identities. This system would specify the dates on which a confidential chemical identity claim must be resubstantiated, identify any actions relevant to that claim, and enable full disclosure of all CBI when all claims are either not eligible for protection, have expired, or have been withdrawn.

* * * * * * *

ACC is very concerned about the legal and resource implications of EPA's approach to implementing the substantiation provisions of the LCSA. ACC recommends EPA take immediate corrective action by halting its current substantiation practices, reassess the approach, and implement appropriate practices that make the best use of the Agency's and industry's resources.

Sincerely,

Michael P. Walls
Vice President
Regulatory & Technical Affairs

cc: Jeff Morris
Wendy Cleland-Hamnett

Appendix A
CDR and PMN elements that should not require substantiation under TSCA.

CDR Form U

Section of Form	Exempt from Substantiation Under 15 U.S.C. 2613(c)(2)…
2.B.5 (2015 domestically manufactured volume)	F
2.B.6 (2015 imported volume)	F
2.B.8 (2015 volume used on site)	F
2.B.9 (2015 volume exported)	F
2.B.10.a-d (Past production volumes	F

Notably, substantiation questions are already included as part of the CDR submission for the following sections. Therefore, a company that has submitted its CDR submission should not receive a substantiation request from EPA.

- 2.A.1 (Chemical identity)
- 2.B.2 (Site identity)
- 3.A (Industrial processing and use)
    - Type of process or use
    - Sector(s)
    - Industrial function category
    - Percent production volume
    - Number of sites
    - Number of workers
- 3.B. (Consumer and commercial use)
    - Product category
    - Consumer or commercial or both
    - Used for products intended for children?
    - Percent production volume
    - Maximum concentration
    - Number of commercial workers reasonably likely to be exposed

PMN Form

Section of Form	Exempt from Substantiation Under 15 U.S.C. 2613(c)(2)…
Page 4, Section B.1.a (Class 1 or 2)	G
Page 4, Section B.1.b (Chemical name and CAS number)	G
Page 4, Section B.1.d (Molecular formula)	G
Page 4, Section B.1.e (Chemical structure diagram)	G
Page 4a, Section B.1.e(1) (Precursor substances)	G
Page 4a, Section B.1.e(2) (Nature of reaction or process)	A
Page 4a, Section B.1.e(3) (Range of composition and typical composition)	G
Page 5, Section B.2.a(i), (ii), (iii) (Polymer number average	G

Section of Form	Exempt from Substantiation Under 15 U.S.C. 2613(c)(2)…
molecular weight, maximum weight % below 500 molecular weight, maximum weight % below 1,000 molecular weight)	
Page 5, Section B.2.b (Monomer/reactant identity, typical composition, and maximum residual)	G
Page 5, Section B.2.d (Chemical name and CAS number)	G
Page 5, Section B.2.e (Chemical structure diagram)	G
Page 6, Section B.3.a and b (Impurity names and CAS numbers, maximum weight %)	G
Page 6, Section B.4 (Synonyms)	G
Page 6, Section B.5 (Trade identification)	G
Page 6, Section B.7(1) and (2) (Byproducts – Name and CAS number)	G
Page 7, Section C.1 (Maximum production volumes – first and third years)	F
Page 7, Section C.2.a (Category of use, production percentage, % in Formulation, % of substance expected per use)	B, E
Page 8, Section A.1.c (Amount and duration of manufacturing/processing/use operations)	F
Page 8, Section A.1.d (Process description)	A
Page 9, Section A.2(1) (Description of worker activity)	A
Page 9, Section A.2(5) (Physical form and % new substance in mixture)	D
Page 9, Section A.2(10) (Hours per day of operation)	A
Page 9, Section A.2(10) (Days per year of operation)	A
Page 9a, Section A.3(2a and 2b) (Amount of substance released)	A
Page 9a, Section A.3(4) (Medium of release)	A
Page 9a, Section A.3(5a) (Control technology)	A
Page 9a, Section A.3(5b) (Amount released after control technology)	A
Page 9a, Section A.3(7) (Destination(s) of releases to water)	A
Page 10, Section B.1(a) (Operation description and site locations for sites controlled by others)	A, C
Page 10, Section B.1(b) (Text description of operation)	A
Page 10a, Section B.2(4a and 4b) (Hours per day and days per year of activity)	A
Page 10a, Section B.2(6) (% new chemical in mixture during activity)	D
Page 10a, Section B.2(7) (% new chemical in final product mixture)	D
Page 10, Section B.2(10a and 10b) (Amount of substance	A

Section of Form	Exempt from Substantiation Under 15 U.S.C. 2613(c)(2)…
released)	
Page 10, Section B.2(12) (Media of release and control technology)	A
Page 10, Section B.2(14) (Byproducts)	G
Page 13 – Spectra	G